Section 5 - 510(k) Summary

This 510(k) summary is being submitted in accordance with 21 CFR § 807.92.

1.1 General Information

Establishment

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Mail Code D02
Malvern, PA 19355, USA
Registration Number 2240869

Manufacturer

Siemens AG
Henkestrasse 127
D-91052 Erlangen, Germany
Registration Number 8010024

SIEMENS MINDIT MAGNETIC RESONANCE LTD.
Siemens MRI Center, Hi-Tech
Industrial park (middle)
Gaoxin C. Ave., 2nd
Shenzhen 518057, P.R. CHINA
Registration Number 3004754211

Contact Person

Ms. Michelle L. Byrne
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Device Name

MAGNETOM Aera and MAGNETOM Skyra with *syngo* MR D11

Please note: syngo MR D11 is the broad name for the software version; it includes all iterations of the software (i.e. the previously cleared software version syngo MR D11A and the subject software update syngo MR D11D).

Classification Name:	Magnetic Resonance Diagnostic Device
CFR Code:	21 CFR § 892.1000
Classification:	Class II
Product Code:	LNH

1.2 Safety and Effectiveness Information Supporting Substantial Equivalence

Device Description

The software and some of the hardware of the previously cleared MAGNETOM Aera and MAGNETOM Skyra have been modified and updated. The updates enable new options, including sequences, applications, coils and coil adapters, for MAGNETOM Aera and MAGNETOM Skyra.

Substantial Equivalence

The modified MAGNETOM Aera and MAGNETOM Skyra are substantially equivalent to the following predicate devices:

Predicate Device Name	510(k) Number	FDA Clearance Date
Siemens MAGNETOM Aera (1.5T) and MAGNETOM Skyra with *syngo*® MR D11A	K101347	October 1, 2010
Siemens MAGNETOM Skyra (3T) with *syngo*® MR D11A	K101347	October 1, 2010
syngo® MR B17 Software update	K082427	November 7, 2008
Siemens MAGNETOM Verio (3T)	K072237	October 10, 2007
Siemens MAGNETOM Espree (1.5T)	K041112	July 21, 2004
Specialty coils for MAGNETOM Aera and MAGNETOM Skyra	K103275	January 11, 2011
Sentinelle Vanguard Breast Coils	K100113	April 22, 2010

Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions USA, Inc. and Siemens AG adhere to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards.

The modified MAGNETOM Aera and MAGNETOM Skyra conform to the applicable FDA recognized and international IEC, ISO and NEMA standards with regards to performance and safety as required by the respective MR FDA Guidance Document.

Intended Use

The MAGNETOM Aera and the MAGNETOM Skyra systems are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross-sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities.

Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis.

The MAGNETOM Aera and the MAGNETOM Skyra systems may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-safe biopsy needles.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

NOV 23 2011

Ms Mitchelle L. Byrne
Regulatory Affairs Technical Specialist
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway, Mail Code D02
MALVERN PA 19355

Re: K111242
Trade/Device Name: MEGNETOM Aera and MAGNETOM Skyra
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 17, 2011
Received: November 18, 2011

Dear Ms. Byrne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 4 - Indications for Use Statement

510(k) Number (if known) K111242

Device Names: **MAGNETOM Aera and MAGNETOM Skyra**

Indications for Use

The MAGNETOM systems described above are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities.

Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis..

The MAGNETOM systems described above may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-safe biopsy needles.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111242